UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: February 9, 1978

SUBJECT: ORTHO Malathion 50 Insect Spray EPA Registration#239-739
Caswell#535 (malathion)

FROM: William Dykstra, Ph.D WBD 2/9/78
Toxicology Branch

TO: Franklin Gee E 2/22/78
Product Manager #16

Action Type: Submission of revised precautionary statements and alternate formulas.

Recommendations:

1. The acute toxicity studies are acceptable as Core-Minimum Data and support the revised precautionary statements and alternate formulas.

2. Although Review#4 is considered as Supplementary Data and does not support the registration, The other eye irritation studies are adequate to support the registration.

*No RPAR Criteria have been exceeded in these studies.

Review:

1. The Acute Oral Toxicity of Ortho Malathion 50 Insect Spray (CHEVRON, S-422, 7/24/72; submitted by Chevron, 9/9/77)

Test Material: Ortho Malathion 50 Insect Spray Five groups of Ten Sprague-Dawley rats (5M + 5F) were intubated with doses of 987, 1481, 2222, 3333, and 5000 mg/kg of test material. After dosing, all animals were observed for signs of toxicity and mortality for 14 days. Necropsy was performed on survivors.

Results: LD_{50} = 2,221 mg/kg

Toxic Signs: Tremors, weakness, ataxia, prostation

Necropsy: No gross pathological changes

Classification: Core-Minimum Data

TOX Category III: CAUTION

2. The Acute Dermal Toxicity od Malathion 50 Insect Spray (CHEVRON, S-319, 7/19/71; submitted by CHEVRON, 9/9/77)

Test Material: Ortho Malathion 50 Insect Spray (Alternate A)

One group of six rabbits received a 2.0 gm/kg dose applied to the shaved back for 24 hours. After dosing period, observations of toxicity and mortality continued for 14 days.

Results: one death $LD_{50} > 2.0$ gm/kg

Toxic Signs: none, moderate skin irritation

Necropsy: No gross pathological change

Classification: Core-Minimum DATA

TOX Category: III CAUTION

3. Skin Irritation Potential of Malathion 50 Insect Spray (CHEVRON, S-319, 7/16/71; submitted 9/9/77)

Test Material: Malathion 50 Insect Spray SX-316

Six rabbits received 0.5 ml of test material on abraded and unabraded shaved areas of the back for 24 hours. Twenty-four hour, 72 hour and seven day scorings of irritation were made using the method of Draize.

Results: At 72 hours P.I. = 3.8/8.0 erythema: moderate; edema: mild
overall: moderate

Classification: Core-Minimum Data

TOX Category: III CAUTION

4. Eye Irritation Potential of Malathion 50 Insect Spray on the eyes of Albino Rabbits (CHEVRON, S-320, 7/22/71; submitted by CHEVRON, 9/977)

Test Material: Malathion 50 Insect Spray

0.1 ml of test material was instilled to the right eye of 6 rabbits. The left eye served as control. Eyes were unwashed and examined at 1, 24, 48, 72 and 7 days after exposure. Scored according to Draize.

Results: Corneal opacity in 3/6 rabbits at 24 hours and 2/6 at 48 and 72 hours. 7 day results not reported. Report states that seven days after testing, all eyes appeared normal.

Classification: Supplementary DATA

(a) Results at 7 days not shown in report.

5. The Eye Irritation Potential of Ortho Malathion 50 Insect Spray (PN 1992) (CHEVRON, S-794, 6/17/75; submitted by CHEVRON, 6/17/75)

Test Material: Malathion 50 Insect Spray Alternate A.

0.1 ml of test material was placed in the conjunctival sac of one eye in each of six rabbits, unwashed, the other eye served as a control. Method of Draizes was used for scoring at 1 hour and at 1, 2, 3, 7, 10 and 14 days.

Results: Corneal opacity in 6/6 rabbits on day 1 and 2, 4/6 rabbits on day 3 and 2/6 rabbits on day 7. 1/6 rabbits on days 10 and 14. Iritis and conjunctivitis present in 5/6 rabbits on day 3 and 1/6 on day 7.

Classification: Core-Minimum Data

TOX Category I: DANGER

6. Rabbit Eye Irritation Test (American Cyanamid Laboratories, SX-885, Report A77-29, submitted by CHEVRON, 9/9/77)

Test Material: Ortho Malathion 50 formula Alternate A

0.1 ml instilled into conjunctival sac of right eye of six rabbits, unwashed. Observation at 4 hours, 24, 48, 72 and 7 days. Scored according to Draize.

Results: Reversible corneal opacity in 7 days - No irritation at 7 days.

Classification: Core-Minimum Data

TOX Category II: WARNING

7. Eye Irritation Study (American Cyanamid Laboratories Report A77-3, Jan. 1977; submitted by CHEVRON, 9/9/77)

Test Material: Ortho 50 Malathion Spray Alternate A

0.1 ml of test material was instilled into right eye of six rabbits, unwashed. Left eye served as a control. Observation at 4 hours, 1, 2, 3 and 7 days. Scored according to Draize.

Results: Reversible corneal opacity at 7 days - No irritation at 7 days.

Classification: Core-Minimum Data

TOX Category II: WARNING

COPY A

Do not use in edible products areas of food processing plants, restaurants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed.

COPY B

frames,

COPY C

behind and under stoves and refrigerators.

COPY D

NOTE:

COPY E

WARNING

COPY F

warnings.

COPY G

WARNING: Causes eye irritation. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Avoid breathing vapors or spray mist. In case of eye contact, immediately flush eyes with fresh water for 15 minutes and get medical attention. If swallowed, promptly drink a large quantity of water and induce vomiting. Get medical attention immediately. Wash skin and hands thoroughly with soap and water after using and immediately in case of skin contact. Remove and launder contaminated clothing before reuse.
Note to Physicians: Emergency Information - call (415) 233-3737. This product contains a cholinesterase inhibitor. If signs and symptoms of cholinesterase inhibition are present, atropine is antidotal. 2-PAM may also be given in conjunction with atropine.